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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,241	04/14/2005	Graham Scott Gutsell	66347-101	9033
68804	7590	01/07/2008		
JOHN P. DE LUCA 17420 RYEFIELD CT. DICKERSON, MD 20842			EXAMINER MITCHELL, TEENA KAY	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 01/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,241	Applicant(s) GUTSELL ET AL.	
	Examiner Teena Mitchell	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-14 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 14 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

Figure 8 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: cage 34. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

IT IS SUGGESTED THAT APPROPRIATED HEADINGS BE PLACED THROUGHOUT THE SPECIFICATION. (note the Headings listed above).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et.al. (WO 00/55072).

Regarding claim 1, Jones discloses a valve mechanism for use in an inhaler comprising a first valve member (22, 20) arranged to be positioned between the pressurised container (page 11, lines 29, 30) and the metering chamber (12), the first valve member being movable between a closed position in which the container is open to the metering chamber, the first valve member being biased to remain in the first position by the pressure in the container; and a second valve member (32, 34) movable between a rest position in which the metering chamber is closed, a metering position in which the valve member actuates the opening of the first valve member to enable a metered dose of medicament to be dispensed into the metering chamber (12), and an open position in which the metering chamber (12) is open to allow medicament to be inhaled.

Regarding claim 2, Jones discloses wherein the first valve member is further biased to remain in the first position by a return spring (26, 36).

Regarding claim 3, Jones discloses wherein the second valve member (32, 34) is arranged to enable the pressure in the metering chamber to assist the opening of the second valve member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et.al. (WO 00/055072).

Regarding claim 4, Jones discloses wherein a surface of the second valve member that contacts the first valve member during metering of a dose, is a cam surface and the first valve member (22, 24) has a cooperating surface, whereby the dose size can be varied (Page 6, lines 26-33, applicant is not claiming what/how the dose is varied only that the dose size can be varied).

Regarding claim 5, Jones discloses wherein a surface at the end of the second valve member that contacts the first valve member (Fig. 1) during metering of a dose is stepped (via spring 26, 36) and the first valve member has a cooperating surface, whereby the dose size can be varied (Page 6, lines 26-33; applicant is not claiming what is actually varying the dose only that the dose is varied).

Regarding claim 6, Jones discloses wherein the second valve member includes a radial seal (32), and wherein movements of the first and second valve members are independent of one another.

Regarding claim 7, Jones discloses wherein the first valve member is a face seal (22).

Regarding claim 8, Jones discloses wherein the end surface of second valve member (34) allows the size of the dose to be adjusted (inherently it does based upon how much of the opening at 30 is covered by element 34, the dose can be adjusted).

Regarding claim 9, Jones discloses the claimed invention except for the cross-section of the first valve member being T-shaped. It would have been an obvious design consideration to one of ordinary skill in the art because the cross-section being in a T-shape would not change the opening or closing of the valve of Jones, it would function the same, therefore the T-shape is deemed to not distinguish over the valve of Jones and is therefore considered a design consideration.

Regarding claim 10, Jones discloses wherein the two valves (22, 24, 32, 34) cannot be opened simultaneously.

Regarding claim 11, Jones discloses wherein the second valve is breath actuated (Page 8, lines 5-11).

Regarding claim 12, Jones discloses incorporating a valve mechanism according to claim 1 connected to a pressurised container (page 11, lines 29, 30).

Regarding claim 14, Jones discloses the second valve can be selected from a plurality of valves with different diameter stems (Page 6, lines 26-33).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et.al. (WO 00/55072) in view of Meshberg (2,974,453).

Regarding claim 13, Jones discloses the claimed invention including an inhaler container except for the claimed manufacturing step. Jones container has a valve stem on the container and Meshberg teaches the filling steps of providing a container (10) to be pressurized by a first valve (16, 17) inserting a material into the container (10) through the first valve (16, 17) and pressurizing and attaching a step (22), the claimed

steps would have been obvious based upon the teaching of Meshberg and because the second valve of Jones is attached after the container is inserted into the device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show inhaler and valve devices: 7,299,801; 2004/0211411; 2003/0106550; 2005/0051162.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Teena Mitchell
Primary Examiner
Art Unit 3771
January 3, 2008


TKM